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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

*(Use as many sheets as necessary)*

Sheet 1 of 2

| *Complete if Known* | |
|---|---|
| Application Number | Divisi nal of 09/835,302 |
| Filing Date | February 5, 2004 |
| First Named Inventor | David Edwards |
| Art Unit | N/A |
| Examiner Name | Not Yet Assigned |
| Attorney Docket Number | 000166.0109-US04 |

**U.S. PATENT DOCUMENTS**

| Examiner Initials* | Cite No.[1] | Document Number Number-Kind Code[2] (if known) | Publication Date MM-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|---|---|---|---|---|---|
| MP | AA | US-3,635,219 | 01/1972 | Altounyan et al. | |
| | AB | US-3,669,113 | 06/1972 | Altounyan et al. | |
| | AC | US-3,795,244 | 03/1974 | Lax et al. | |
| | AD | US-3,837,341 | 09/1974 | Bell | |
| | AE | US-3,888,253 | 06/1975 | Watt et al. | |
| | AF | US-3,906,950 | 09/1975 | Cocozza | |
| | AG | US-4,013,075 | 03/1977 | Cocozza | |
| | AH | US-4,069,819 | 01/1978 | Valentini et al. | |
| | AI | US-4,105,027 | 08/1978 | Lundquist | |
| | AJ | US-4,192,309 | 03/1980 | Poulsen | |
| | AK | US-4,240,418 | 12/1980 | Rosskamp et al. | |
| | AL | US-4,860,740 | 08/1989 | Kirk et al. | |
| | AM | US-4,889,114 | 12/1989 | Kladders | |
| | AN | US-4,995,285 | 02/1991 | Valentini et al. | |
| | AO | US-5,152,284 | 10/1992 | Valentini et al. | |
| | AP | US-5,239,992 | 08/1993 | Bougamont et al. | |
| | AQ | US-5,301,666 | 04/1994 | Lerk et al. | |
| | AR | US-5,349,947 | 09/1994 | Newhouse et al. | |
| | AS | US-5,524,613 | 06/1996 | Haber et al. | |
| | AT | US-5,595,175 | 01/1997 | Malcher et al. | |
| | AU | US-5,647,349 | 07/1997 | Ohki et al. | |
| | AV | US-5,651,359 | 07/1997 | Bougamont et al. | |
| | AW | US-5,673,686 | 10/1997 | Villax et al. | |
| | AX | US-5,685,294 | 11/1997 | Gupte et al. | |
| | AY | US-5,727,546 | 03/1998 | Clarke et al. | |
| | AZ | US-5,740,794 | 04/1998 | Smith et al. | |
| | AA1 | US-5,785,049 | 07/1998 | Smith et al. | |
| | AB1 | US-5,797,391 | 08/1998 | Cook et al. | |
| | AC1 | US-5,810,004 | 09/1998 | Ohki et al. | |
| | AD1 | US-5,860,419 | 01/1999 | Davies et al. | |
| | AE1 | US-5,896,855 | 04/1999 | Hobbs et al. | |
| | AF1 | US-5,921,237 | 07/1999 | Eisele et al. | |
| | AG1 | US-6,092,522 | 07/2000 | Calvert et al. | |
| | AH1 | US-6,102,035 | 08/2000 | Asking et al. | |
| | AI1 | US-6,116,237 | 09/2000 | Schultz et al. | |
| | AJ1 | US-6,116,238 | 09/2000 | Jackson et al. | |
| | AK1 | US-6,142,145 | 11/2000 | Dagsland et al. | |
| ✓ | AL1 | US-US 2003/0094173-A1 | 05-22-2003 | Burr et al. | |

| Examiner Signature | | Date Considered | 6/26/04 |
|---|---|---|---|

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| Examiner Name | Not Yet Assigned |
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## FOREIGN PATENT DOCUMENTS

| Examiner Initials* | Cite No.[1] | Foreign Patent Document: Country Code[3]-Number[4]-Kind Code[5] (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T[6] |
|---|---|---|---|---|---|---|
| MP | BA | WO-WO 94/08552-A2 | 04-28-1994 | Mecikalski et al. | | |
| | BB | WF-WO 00/64519-A1 | 11-02-2000 | Haikarainen et al. | | |
| | BC | WO-WO 01/07107 | 02/2001 | Pharmaceutical Discovery Corporation | | |

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## NON PATENT LITERATURE DOCUMENTS

| Examiner Initials* | Cite No.[1] | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T[2] |
|---|---|---|---|
| MP | CA | Bisgaard, H. et al., Fine particle mass from the Diskus inhaler and Turbuhaler inhaler in children with asthma, European Respiratory Journal, 11: 1111-1115, May 1998. | |
| | CB | de BOER, A.H. et al., "Inhalation characteristics and their effects on in vitro drug delivery from dry powder inhalers, Part 1. Inhalation characteristics, work of breathing and volunteers' preference in dependence of the inhaler resistance," International Journal of Pharmaceutics 130: 231-244 (1996). | |
| | CC | Dunbar, Craig A. et al., A Comparison of Dry Powder Inhaler Dose Delivery Characteristics Using a Power Criterion, PDA Journal of Pharmaceutical Science & Technology, 54(6): 4780484, November/December 2000. | |
| | CD | Feddah, Majid R. et al., In-Vitro Characterisation of Metered Dose Inhaler Versus Dry Powder Inhaler Glucocorticoid Products: Influence of Inspiratory Flow Rates, J. Pham. Pharmaceut. Sci. (www.ualberta.ca/-csps) 3(3): 317-324 (2000). | |
| | CE | Koskela, T. et al., Efficacy of salbutamol via Easyhaler@ unaffected by low inspiratory flow, Respiratory Medicine 94: 1229-1233 (December 2000). | |
| | CF | Nielsen, K.G. et al., Flow-dependent effect of formoterol dry-powder inhaled from the Aerolizer@, European Respiratory Journal, 10: 2105-2109 (September 1997). | |
| | CG | Richards, Robert and Saunders, Michael, Need for a comparative performance standard for dry powder inhalers, Thorax 48: 1186-1187 (November 1993). | |
| | CH | Ross, Danna L. and Schultz, Robert K., Effect of Inhalation Flow Rate on the Dosing Characteristics of Dry Powder Inhaler (DPI) and Metered Dose Inhaler (MDI) Products, Journal of Aerosol Medicine, 9: 215-226 (November 2, 1996). | |
| | CI | Smith, Karen J. et al., Influence of Flow Rate on Aerosole Particle Size Distributions from Pressurized and Breath-Actuated Inhalers, Journal of Aerosol Medicine, 11: 231-245 (November 4, 1998). | |

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